REMARKS

In the Office Action, dated July 9, 2008, the Examiner states that Claims 1-5 and 7 are pending and rejected. By the present Amendment, Applicant amends the specification, the claims, and the drawings.

1. Rejection of Claims 1-3 under 35 U.S.C. 102(b)

Claims 1-3 are rejected under 35 U.S.C. 102(b) as anticipated by Sass (US 2002/0058978) for the reasons of record. Applicant respectfully disagrees with and traverses this rejection.

Applicant respectfully indicates that Claim 1 is directed to a *percutaneous* cable, whereas Sass is directed to a subcutaneous cable (see paragraph [0004]). Applicant further indicates that currently amended Claim 1 includes the subject matter of claim 4, which the Office Action did not indicate as anticipated by Sass. Applicant respectfully asserts that Sass does not anticipate a percutaneous lead assembly in two portions, which are releasably mutually connectable wholly externally to the patient's body. In contrast, Sass discloses a coaxial cable, which by definition does not include mutually connectable connectors between different regions of the cable, and at any rate has no portion configured to be external to the body.

Accordingly, Applicant respectfully asserts that the rejected claims are not anticipated by Sass under 35 U.S.C. 102(b) and respectfully requests withdrawal of the present rejection.

2. Rejection of Claims 4, 5 and 7 under 35 U.S.C. 103(a)

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as obvious over Sass in view of Jarvik (US 5,904,646) for the reasons of record. Claim 7 is rejected under 35 U.S.C. 103(a) as obvious over Sass and Jarvik in view of Imran et al. (US 5,449,381) for the reasons of record. Applicant respectfully disagrees with and traverses these rejections.

As previously noted, Sass teaches a subcutaneous coaxial cable. Sass is provides absolutely no guidance on percutaneous uses and therefore is not relevant when considered in light of the present invention or in combination with the percutaneous lead of Jarvik. Being subcutaneous, Sass does not have the same issues as a percutaneous lead. Jarvik teaches a connection system for joining a

subcutaneous lead to an extracorporeal lead. The connection system requires one connector to be bone mounted and percutaneous (see Fig. 6). Jarvik notes that a problem with percutaneous leads is trauma of the tissues where the device penetrates the skin, which can cause infection (column 1, lines 25 to 30). He also notes that one way of reducing such trauma is by anchoring the percutaneous lead to bone to prevent motion of the lead (Column 1, lines 31 to 35). Jarvik therefore very clearly and distinctly teaches the anchoring of a percutaneous lead to bone. Jarvik quite demonstrably teaches away from not having a percutaneous lead anchored to bone, for fear of skin trauma. Jarvik's invention is in fact directed to "an internal connector 30" (Column 3, line 37) for anchoring to the skull bone of a patient. The connector of Jarvik is only taught as being anchored to bone, and cannot be interpreted as being free floating. To be free floating would be against the teaching of Jarvik who states that skin trauma can occur when the lead is not anchored. As the connector is anchored to bone (in the preferred embodiment of Jarvik, to the patient's skull), it can only be considered as either a percutaneous connector (as is in fact illustrated in Figure 6 of Jarvik), or at most a subcutaneous connector, however, it is not possible for the connector to be interpreted as extracorporeal. Applicant respectfully asserts that if one of ordinary skill in the art were to read Jarvik, they would not find any suggestion or motivation to arrive at an extracorporeal connection arrangement as Jarvik clearly teaches away from such an arrangement.

The rejected claims, on the other hand, do not require bone anchoring of connectors as required by Jarvik. In contrast, the rejected claims define connectors which connect wholly externally of the patient's body. This reduces the complicated configuration of Jarvik, which requires implantation and screw mounting of a connector to the patient's skull, while also preparing an exit wound to accommodate the percutaneous exit of the skull mounted connector. Furthermore, given that the connectors of the present invention are external to the patient, only the lead exists the wound site, meaning the wound site is smaller compared to the wound site of Jarvik's connector. Meanwhile, the present invention still has the advantage of allowing disconnection of the second portion of the lead assembly external to the patient, thus not requiring an operative procedure for disconnection. As such, Applicant respectfully asserts that the rejected claims are not obvious under 35 U.S.C. 103(a) over Sass in view of Jarvik.

With respect to the rejection of Claim 7, neither Sass nor Jarvik teach or suggest the joining of two lead portions external to the body of a patient. Imran et al., being related to a fully implantable endocardial catheter for peacemakers, etc, is equally silent on such a feature.

Since each and every feature of Claim 7 is not taught or suggested in the cited prior art, Applicant respectfully asserts that this claim is not obvious under 35 U.S.C. 103(a) over Sass and Jarvik in view of Imran et al.

Finally, Applicant has added new Claims 8-12. These claims are concerned with the relative diameters of the internal and external cables of the present invention. For sake of completeness, we submit that, in respect of two leads portions being connectable together, as in amended Claim 1, the teaching of Sass is contextually different than Claims 8-12. That is to say, Claims 8-12 imply a serial connection of elongate member portions, whereas the lead of Sass is coaxial.

The purpose of the different diameters of the lead portions of the present invention is wholly different than the reason for lead portions of Sass being different. The lead portions of Sass are of different diameter to allow the smaller diameter lead to fit within the larger diameter lead portion, as they are coaxial. The lead portions of the present invention are of different diameters for a different reason. The smaller diameter lead portion is configured to exit the skin, while the larger diameter lead portion is configured to be external to the patient. Furthermore, in practice, the extracorporeal portion preferably has additional layers compared to the percutaneous portion to protect it from damage, which may occur from external events, such as extracorporeal lead movement, abrasion, etc, compared with the internal part of the percutaneous portion. In the meantime, Applicant has found that it is preferred that the percutaneous portion be as small as possible to reduce risks associated with the exit wound, such as infection. Applicant has discovered that the additional shielding-type layers preferred to be on the extracorporeal portion are not required on the percutaneous portion. Therefore, the percutaneous portion can have a smaller diameter than the extracorporeal portion. This is neither contemplated, nor suggested in Jarvik, and the resultant claimed features cannot be inferred from either Sass, Jarvik, or Imran et al., or a combination of these references. In the interest of expediting prosecution, Applicant respectfully asserts that Claims 8-12 are not

anticipated by or rendered obvious over the cited prior art for at least the aforementioned reasons in combination with the fact that they are dependent upon allowable independent Claims 1 and 7.

In light of the foregoing response, all the outstanding objections and rejections are considered overcome. Applicant respectfully submits that this application should now be in condition for allowance and respectfully requests favorable consideration.

Respectfully submitted,

October 8, 2008
Date

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